

HUMAN FACTORS AND USABILITY STUDY

Understanding Participant Reactions to Activ-Blister™ Solutions Active Packaging

Background and Introduction

Oral solid dosage (OSD) form drugs make up nearly 24% of the global pharmaceutical drug delivery market.¹ This route of administration is the most convenient, often the safest, and in most cases, least expensive. However, OSD drugs delivered in a blister packaging format face growing stability challenges associated with moisture, oxygen and reactive impurities, which could result in potency loss or degradant growth.

Aptar Active Material Science's proprietary 3-Phase Activ-Polymer™ platform technology enables development of a new class of highly-engineered polymer compounds that can be configured to provide customized product protection for sensitive drug products, probiotics, medical devices, drug delivery systems, and even foods. When deployed as Activ-Blister™ Solutions, the technology creates a precise microclimate within individual blister cavities to protect tablets or capsules inside a thermoformed blister package, delivering improved product performance and enhanced shelf life.

Objectives

To support successful adoption of Activ-Blister™ technology, it is critical that the patient experience is not disrupted. As part of the drug development process, the sponsor must prove that the finished pharmaceutical product can be used safely and effectively by the targeted patient population. To support this requirement, we conducted a third-party formative Human Factors study that explored the drug dispensing experience, ease of use, user reactions to the integrated Activ-Film™ material that is part of the Activ-Blister™ solution, and impact of de-blistering on the tablet or capsule.

Methods

For this study, participants were given Activ-Blister™ cards holding placebo tablets and capsules, with headspace modification film (Activ-Film™ material) affixed to the foil (Figure 1). Cards were the same design for both the tablet and capsule placebos and did not have a child resistant feature.

A panel of forty (40) participants who take prescription medications on their own without assistance participated in the study. The panel was comprised of two sub-panels of adults (ages 21 to 65) and minors (ages 12 to 20), with approximately equal gender distribution among each sub-panel. About half of the participants in this study evaluated the Activ-Blister™ Solutions card with tablets and half evaluated the card with capsules.

For the evaluation process, respondents participated in individual, in-person interviews which consisted of a combination of observational and direct questioning techniques. During the interviews, respondents were asked about their perception of the ease of opening the package (based on visual cues, before removing a tablet or capsule). Without being given any directions, they were then asked to open the package and remove a tablet/capsule. Participants' actions were recorded using direct observation during this part of the process. After each respondent completed the opening process, they were asked a series of questions about the package attributes and the Activ-Film™ material (Figure 2).

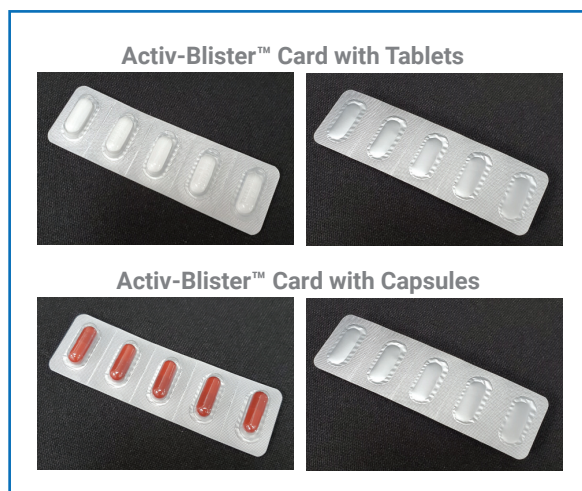


Figure 1: Activ-Blister™ Solutions Placebo Cards

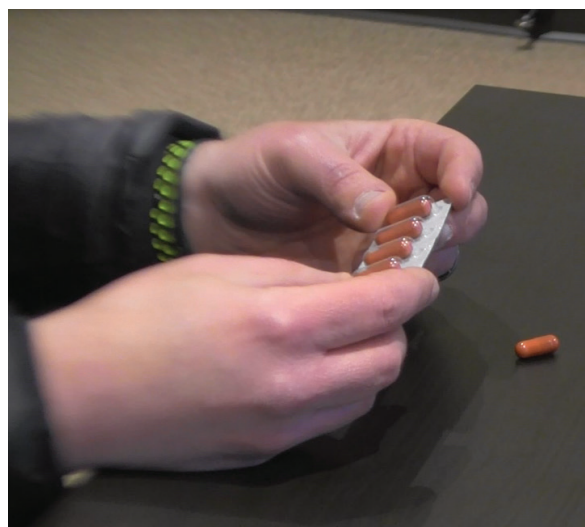


Figure 2: Human Factors Study Participant Interacting with Activ-Blister™ Placebo Card

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Results

PARTICIPANT SCORES FOR EASE-OF-USE

PERCEIVED

9.1 OUT OF 10

Perceived ease-of-use scores were **8.5** for tablets and **9.1** for capsules out of 10 possible points.

ACTUAL

9.7 OUT OF 10

Actual ease-of-use scores were **9.7** for both placebo forms.

Positive scores among participants confirmed that Activ-Blister™ cards were easy to use. Nearly all respondents removed a pill from the package in two seconds or less.

OPENING THE PACKAGE

Participants opened the package in various ways.

- 29 out of 40 participants pushed the pill through the blister card.
- 8 participants punctured the foil and peeled it back to access the pill.
- 3 participants pushed the pill through the blister card, punctured the foil, and peeled it back to access the pill.

No damage occurred to any of the tablets or capsules during the de-blistering process.

When asked, most respondents (36 out of 40) had no concerns with the package, and none of the respondents mentioned the Activ-Film™ material on the foil during the de-blistering process. The four comments made were unrelated to the integrated Activ-Blister™ technology.

PARTICIPANT RESPONSES TO ACTIV-FILM™

About two-thirds of the participants (28) said they noticed the Activ-Film™ material (hard piece) on the foil. When asked what they thought the purpose of the Activ-Film™ material was, most thought it was to help protect the pill or to help with opening the package.

Participant Comments on Perceived Purpose of Activ-Blister™ Film

- Protect the pill so it does not break / more secure than foil
- Keep pill from popping out on accident
- Make it tamper evident
- Protect seal / keep it sealed
- Make it easier to open / help pill come out

Most of the respondents (39) did not feel the Activ-Film™ material on the foil caused any concerns and most (37) assumed they did not need to do anything with the Activ-Film™ material on the foil.

No respondents assumed the Activ-Film™ material was part of the pill.

Conclusions and Insights

Activ-Blister™ Solutions can be implemented without a negative impact on patient experience, giving them an equivalent experience to what they would have with regular blister packaging, but with the added protection inside blister cavities that sensitive API's need. Activ-Blister™ cards were easy to use for consumers and the integrated film did not cause any concern during the de-blistering process. Rather, the film was perceived positively as a way to protect the pill or make the package easy to use. Activ-Film™ material affixed to the foil does not present any risks or confusion to the users of the product, as it was not perceived to be part of the tablet or capsule and was left alone — no respondent attempted to separate the Activ-Film™ material from the foil. Aptar Active Material Science's integrated active material science solutions assure drug stability and potency in a format that delivers a seamless and improved patient experience.